SUMMARY STATEMENT-DRAFT
(Privileged Communication)

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Application Number: 1 P01 ES014975-01

Miranda, MARIE L PHD
DUKE UNIVERSITY
BOX 90328
A134 LEV SCI RES CTR
DURHAM, NC 27708-0328

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ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

Administrative Note: p. 12, 17

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DESCRIPTION (provided by applicant)

Adverse birth outcomes exhibit disparities across subpopulations. Although it is widely agreed that birth outcomes are determined by multiple forces, surprisingly little is known about the interaction of those forces and how those forces jointly drive health disparities. Elevated environmental exposures often occur in communities facing multiple social stressors, which may compound the effects of environmental exposures. This phenomenon is especially severe for low income and minority pregnant mothers, with significant health implications for the fetuses they carry. In addition, despite the growing importance placed on gene environment interactions, we know little about how genetic and environmental factors combine differentially to promote or prevent adverse birth outcomes across subpopulations. The central mission of the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO) is to determine how environmental, social, and host factors jointly drive health disparities in birth outcomes. Specific goals of the Center are: 1) to develop and operate an interdisciplinary children's health research center with a focus on understanding how biological, physiological, environmental, and social aspects of vulnerability contribute to health disparities; 2) to enhance research in children's health at Duke by promoting research interactions among programs in biomedicine, environmental health, and the social sciences and establishing an infrastructure to support and extend interdisciplinary research; 3) to develop new methodologies for incorporating innovative statistical analysis into children's environmental health research and policy practice, with a particular emphasis on genetic and spatial analysis; 4) to serve as a technical and educational resource to the local community, region, the nation, and to international agencies in the area of children's health and

health disparities; and 5) to translate the results of the Center into direct interventions in clinical care and practice. SCEDDBO will leverage active partnerships among Duke's School of the Environment, Medical Center, and School of Arts and Sciences, as well as community organizations. Survivors of poor birth outcomes are at significant risk for neonatal, infant, and child morbidity and mortality, as well as obesity, cardiovascular disease, and diabetes in adulthood. Thus understanding, and eventually intervening, to prevent adverse birth outcomes is of critical importance to the overall health of the nation.

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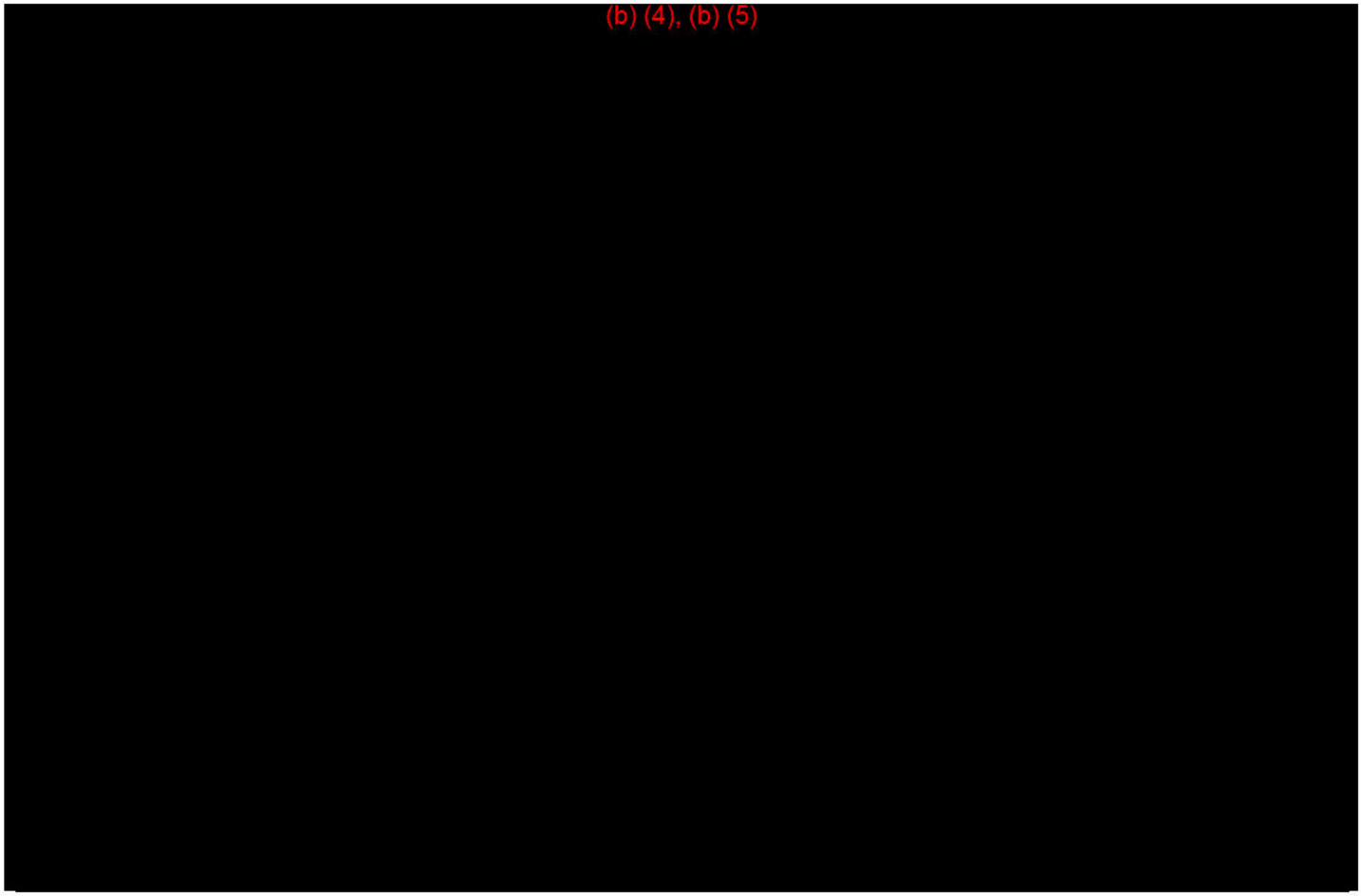

ADMINISTRATIVE CORE (Miranda)

DESCRIPTION (provided by applicant): The Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO) will be governed through an Administrative Core that includes an Executive Committee composed of the Director, the two co-Directors, and the Project Manager; an Internal Steering Committee composed of members of the Executive Committee and the Directors of the Research Projects and the Facility and Community Outreach Cores, as well as a community member and the Director of the Durham County Health Department; and an External Advisory Committee composed of senior environmental health scientists, as well as community representatives, with expertise relevant to SCEDDBO, who will provide informal consultation as well as annual formal evaluation of Center research and outreach activities. The specific aims of the Administrative Core are to: a) provide scientific direction and leadership; b) coordinate and foster interactions among Research Project and Facility Core investigators; c) provide administrative services for the Center; d) direct the New Investigator Program; and e) represent SCEDDBO to the university, the community, the NIH, other children's environmental health centers

across the United States, and the policy and scientific community interested in children's environmental health more broadly. SCEDDBO will emphasize the importance of diversity in all its activities. The decision to focus on health disparities, the gender and racial diversity of Center leadership, the incorporation of natural, social and biomedical scientists, a commitment to community-based participatory research, and efforts to promote the careers of promising new investigators are all indicative of the importance that the investigators place on fostering environments where all people can prosper.

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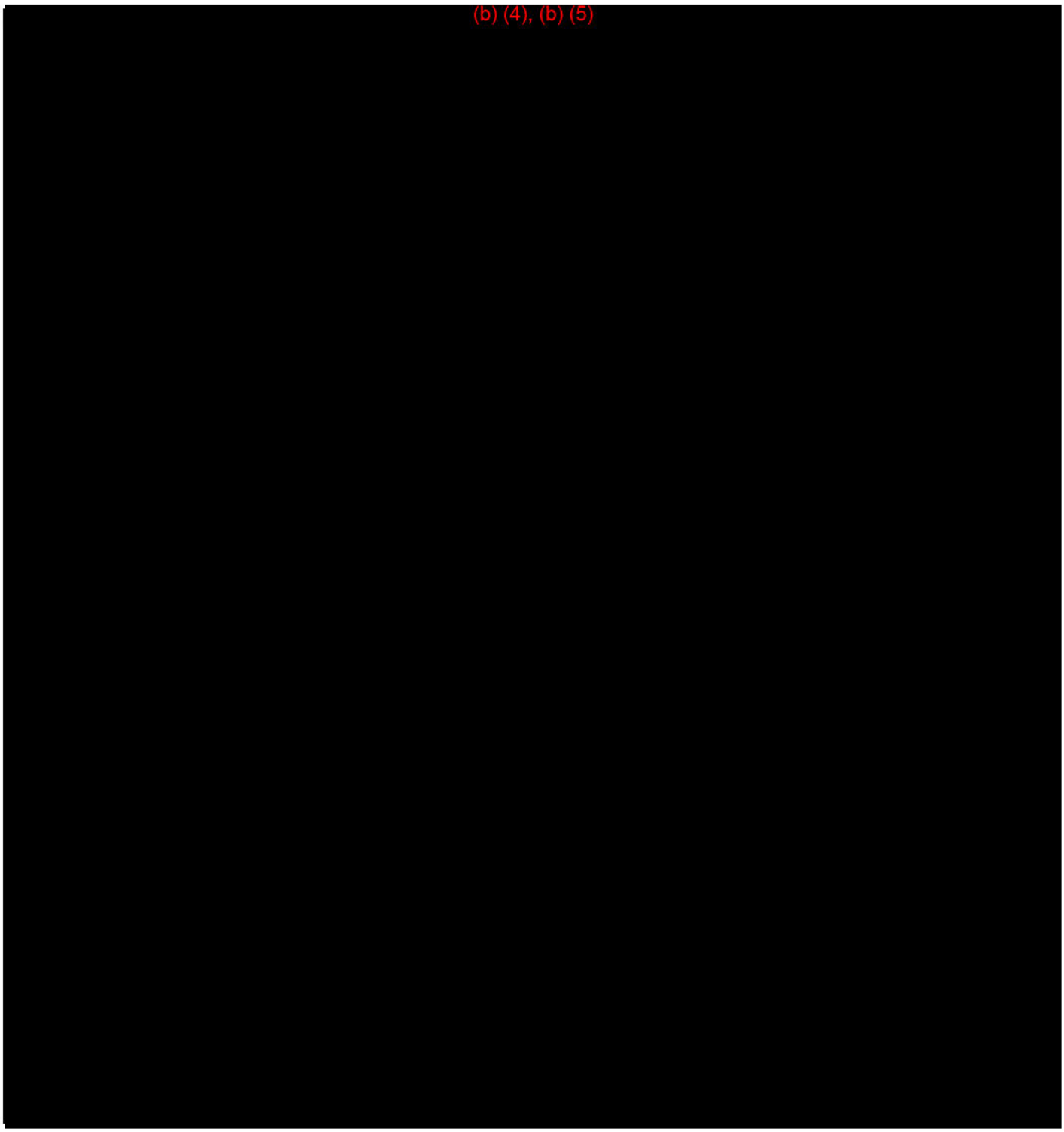

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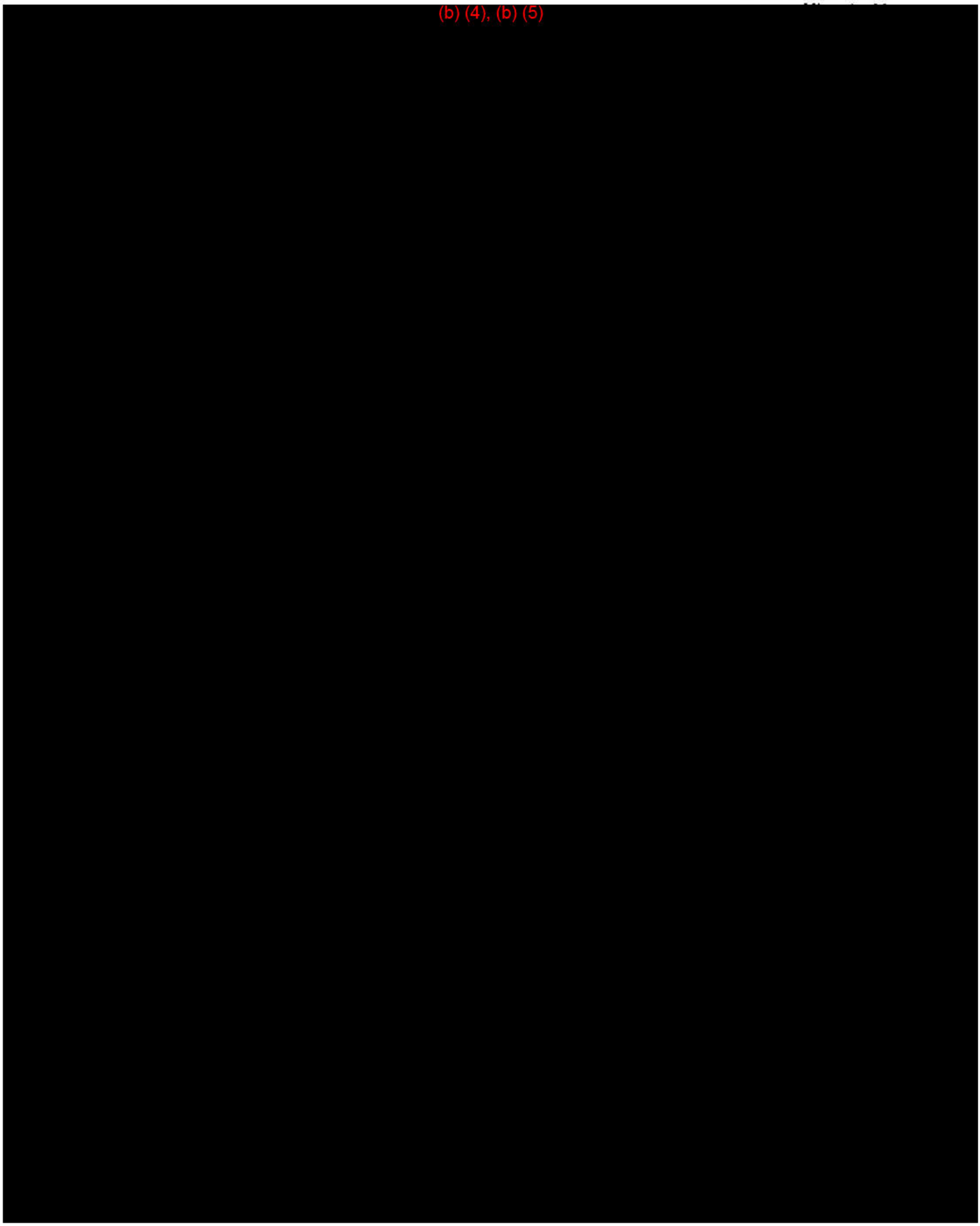

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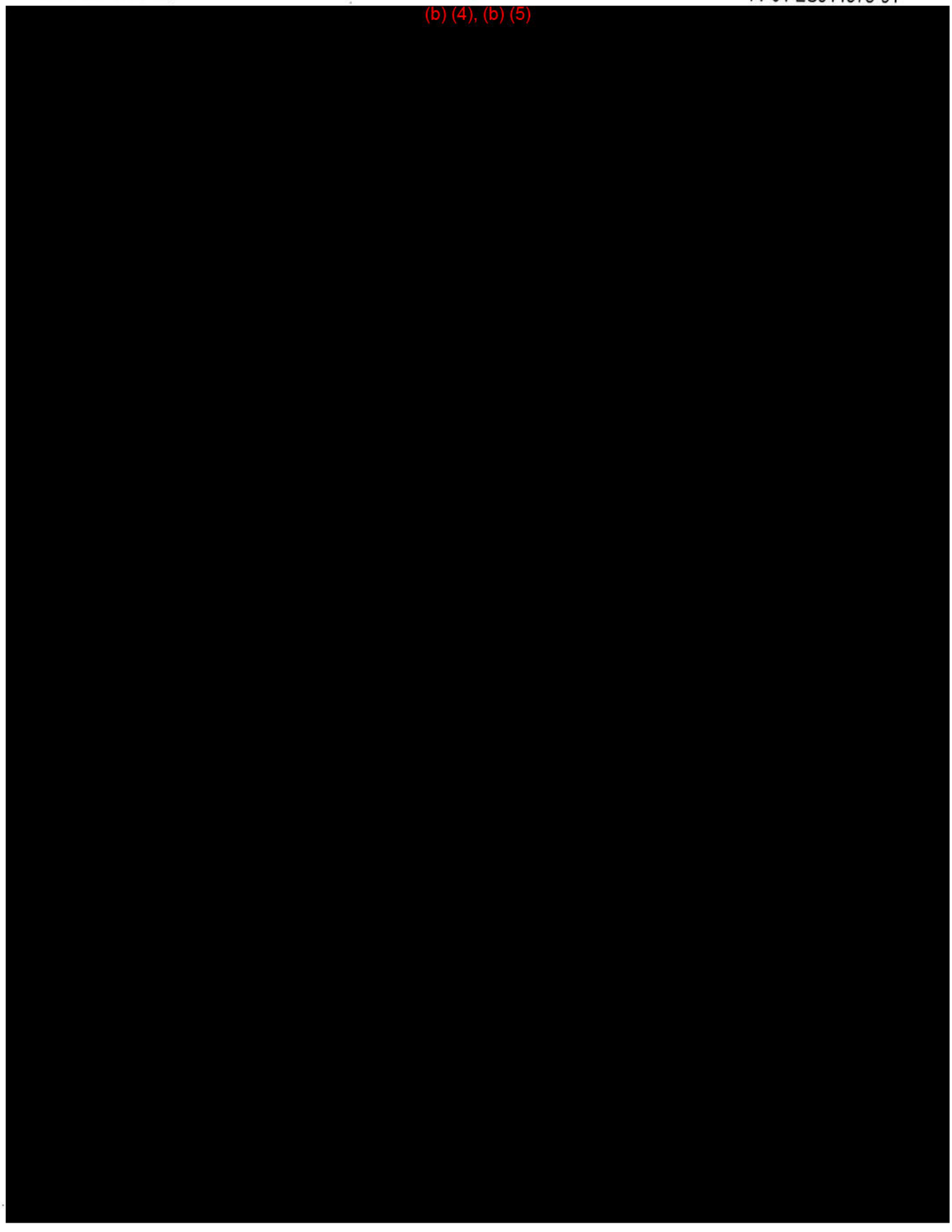

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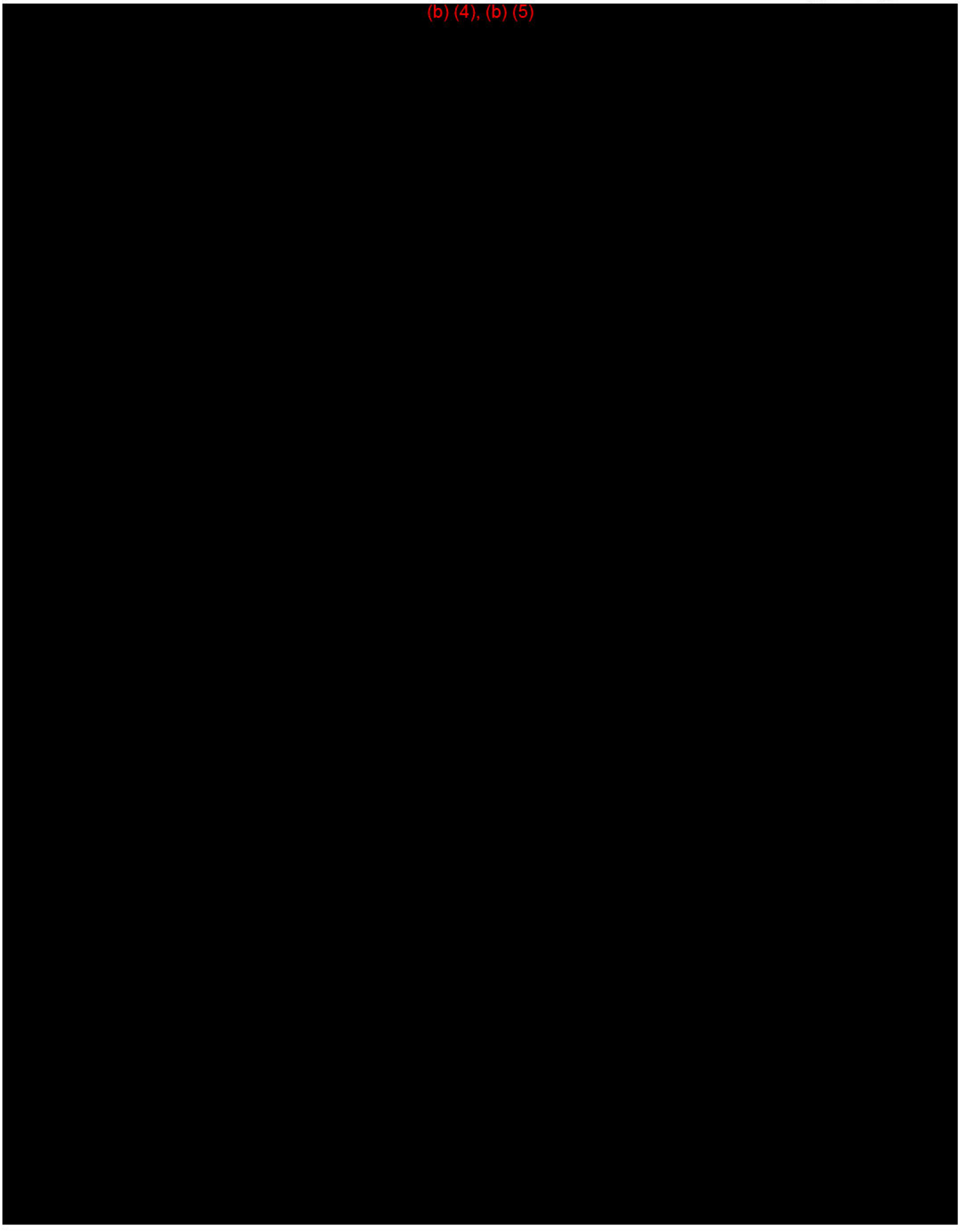

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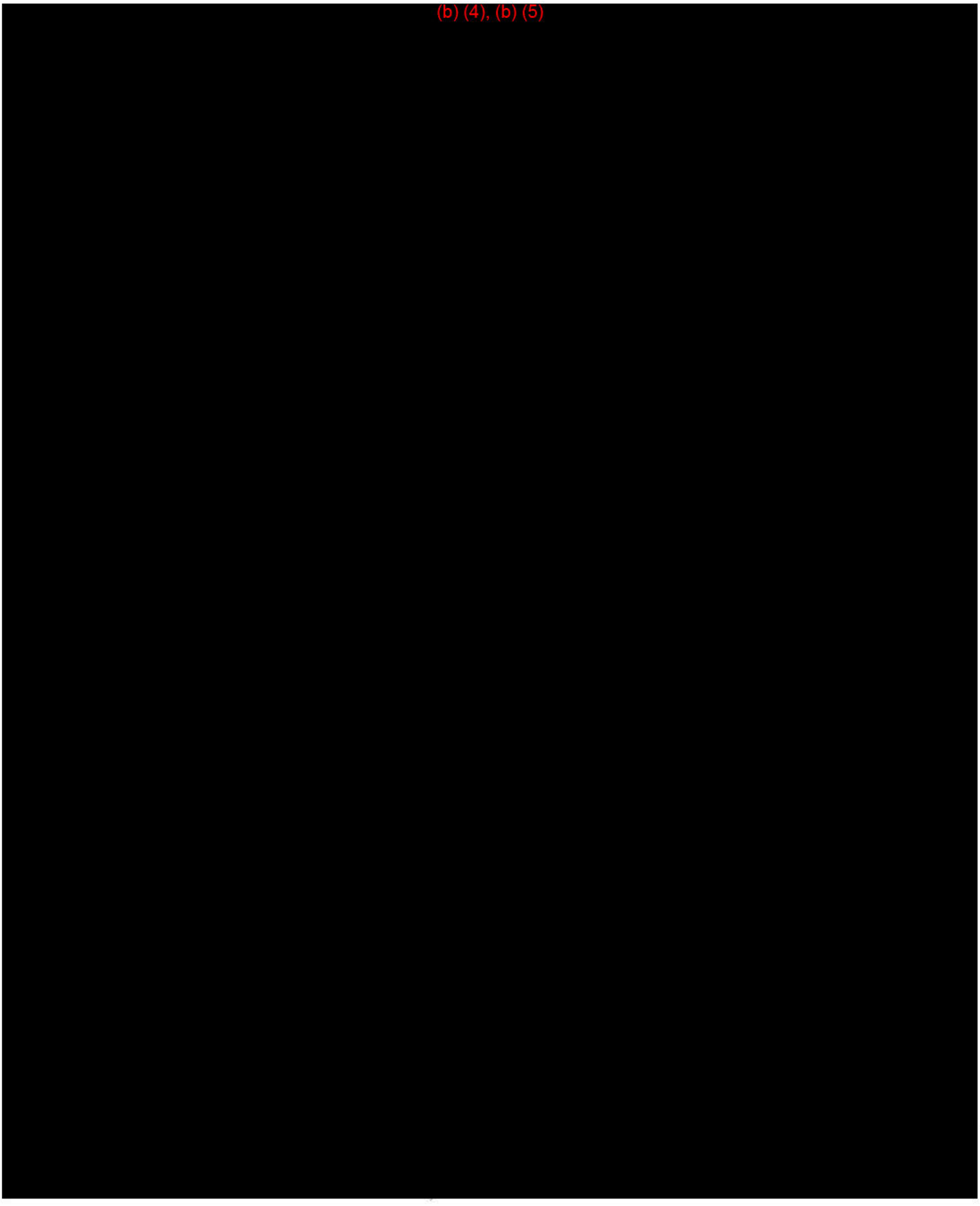

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NOTE

The comments above were prepared by the reviewers assigned to this application. They are provided to illustrate the opinions expressed. The application was discussed and scored by all reviewers present, although any committee member having a conflict of interest was absent during the discussion and scoring. The attached commentaries do not necessarily reflect the position of the assigned reviewers at the close of the group discussion nor the final majority opinion of the group, although reviewers were asked to amend their commentaries if their positions changed during the discussion of an application. The resume and other initial sections of the summary statement are the authoritative representation of the final outcome of group discussion. If there is any discrepancy between the peer reviewers' commentaries and the numerical score on the face page of this summary statement, the numerical score should be considered the most accurate representation of the final outcome of the group discussion.

NOTICE: The NIH has modified its policy regarding the receipt of amended applications. Detailed information can be found by accessing the following URL address: http://grants.nih.gov/grants/policy/amendedapps.htm

NIH announced implementation of Modular Research Grants in the December 18, 1998 issue of the NIH Guide to Grants and Contracts. The main feature of this concept is that grant applications (R01, R03, R21, R15) will request direct costs in $25,000 modules, without budget detail for individual categories. Further information can be obtained from the Modular Grants Web site at http://grants.nih.gov/grants/funding/modular/modular.htm

MEETING ROSTER

National Institute of Environmental Health Sciences Special Emphasis Panel
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
ZES1 LKB-A (C1) P
March 09, 2006 - March 11, 2006

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Designating Priority Scores

As stated in NCI publication (No.05-122), "Everything you wanted to know about the NCI Grants Process but were afraid to ask", pp. 50-51.
Available in pdf at http://www3.cancer.gov/admin/qab/2005GPB/GPB05-HighRes.pdf

At present, the review committee may make one of the following recommendations regarding scoring an application:

- **Scoring:** Applications that are judged to have significant and substantial merit are assigned a priority score. The NIH uses a scale of 1.0 (highest merit) to 5.0 (lowest merit) to score applications during the initial or first level of the scientific review process. Those applications that score in the upper half (1.0 to 3.0) with respect to scientific merit are recommended for the second level of peer review (Advisory Council/Board) by the SRG.
- **Not Scoring:** Applications that are considered to be in the lower half are designated as unscored and are not given a numerical score. These applications are not discussed in the review meeting. Not scoring an application requires unanimous consent.
- **Not Recommended for Further Consideration (NRFC):** Applications that lack significant and substantial merit or have serious ethical problems in the protection of human subjects from research risks or in the use of vertebrate animals are designated Not Recommended for Further Consideration (NRFC). Applications designated as NRFC do not proceed to the second level of peer review (Advisory Councils/Boards) because they cannot be funded.
- **Deferral (DF):** Applications may be deferred if additional information is needed to make a definitive recommendation.

All SRG members who participate in person or by teleconference, video conference, or virtual meeting (as members of an Internet-assisted meeting) in the evaluation of an application may vote and score the applications. (SRG members with a conflict of interest may not participate in the discussion of an application and may not vote on or score the application for which the conflict exists).

Priority Scores

To determine the priority score, each SRG member assigns a numerical rating that reflects the reviewer's assessment of the overall impact the project could have on the field. This assessment is based on consideration of the five review criteria (significance, approach, innovation, investigators, and environment), with the emphasis on each criterion varying from one application to another, depending on the nature of the application and its relative strengths. The numerical ratings range from 1.0 (best) to 5.0 (worst), with increments of 0.1. A score of 3.0 is the midpoint score; the range of scores from 1.0 to 3.0 represents the upper half of the applications, while applications with scores greater than 3.0 represent the lower half. After the review meeting, the SRA averages the individual reviewers' ratings for each scored application and multiplies by 100 to provide a three-digit number that is the priority score. Generally, 4 to 5 months will have elapsed since the Principal Investigator submitted the application (see Figure 10, p. 47).

Percentile Rank

In addition to a priority score, most applications reviewed by the CSR receive a percentile rank. The conversion of priority scores to percentile rankings (along a 100.0 percentile band) is based on scores assigned to applications reviewed during the current plus the past two review rounds. Applications reviewed by a standing study section are ranked against all applications reviewed by that same study section over the three consecutive rounds. Applications reviewed by NCI review groups receive priority scores only, and percentile ranks are not calculated for these applications. The overall intent of percentile ranking (or "percentiling") is to improve the comparability of scored applications across SRGs and to minimize the impact of round-to-round quality variation. The percentile/priority score is the primary indicator of relative scientific merit when applications are being considered for funding within an Institute.

17 May 2006

Dr. Kimberly Gray
Susceptibility and Population Health Branch
Division of Extramural Research and Training, NIEHS
Research Triangle Park, NC 27709

Dear Dr. Gray:

My collaborators and I read with interest the summary statement on 1P01ES014975-01, the Southern Center on Environmentally-Driven Disparities in Birth Outcomes (SCEDDBO). We are grateful to the study section for their thoughtful and careful review of our proposed center. In response to the summary statement, we offer several observations:

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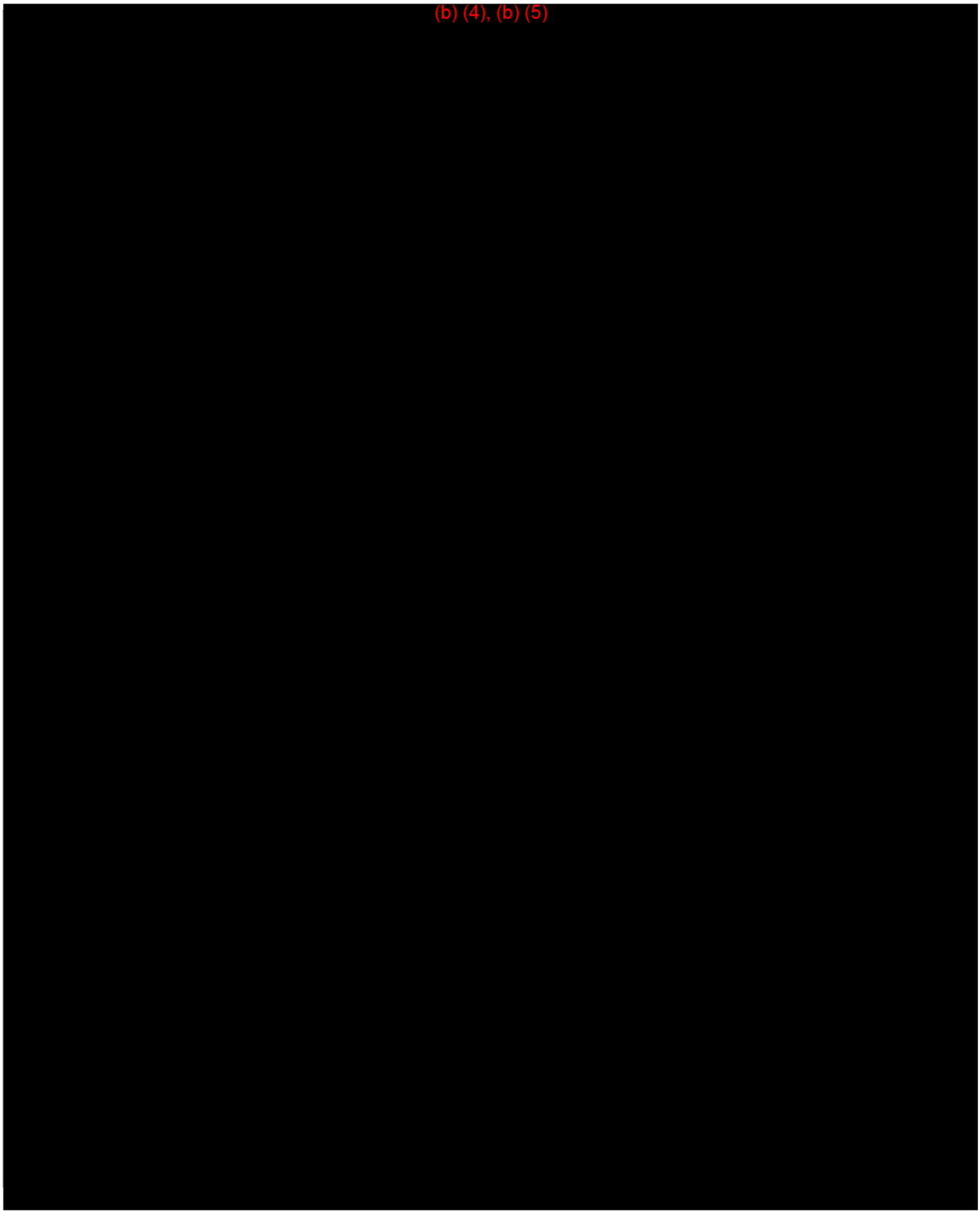

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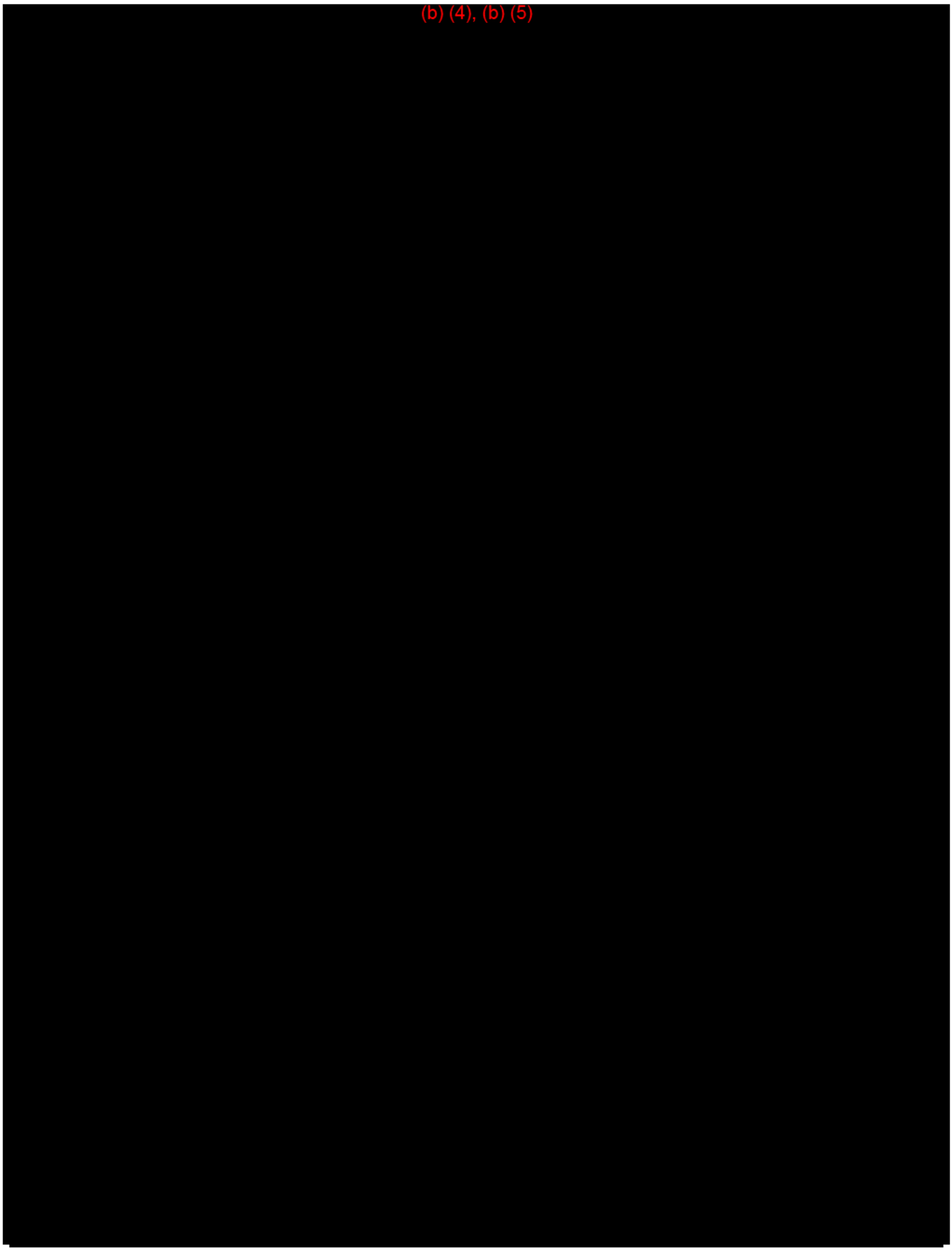

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Many thanks for allowing us the opportunity to respond to the summary statement. We look forward to hearing from you.

Regards,

(b) (6)

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Marie Lynn Miranda, Ph.D.

Programmatic Terms and Conditions

1. Advisory Committee

a. The Center Director will establish and maintain a **Science Advisory Committee** (SAC). EPA recommends that the SAC consist of approximately nine to twelve individuals who are experts in technical fields related to the goals of the Center. The function of this Committee is to assist in evaluating the merit, value and contribution of research projects, and the relevance and importance of individual organizational elements to accomplishing the overall goals of the Center. The Committee will elect a chair and vice-chair from among its members. The EPA Project Officer will serve as a non-voting observer. The SAC must meet at least once a year to discuss progress of Center activities unless a different schedule is approved by the EPA. The Center Director must maintain records of any decisions he or she proposes which deviate from the recommendations of the SAC.

b. The committee must have an appropriate balance of members from academia, industry, environmental organizations, and governmental entities, representing a range of opinions and environmental disciplines.

2. Reporting.

a. **Overview.** The recipient agrees to provide EPA's Project Officer *annual Center progress reports* with associated *annual research project summaries*, and a *final Center report* with *final project summaries*, along with a copy of or reference for any papers resulting from the research conducted. Requirements for the content of reports and summaries are stated below. Any detail specific to this Center in addition to those below may be established by the Project Officer and negotiated with the Center Director in advance, provided the frequency of reporting is not more than quarterly.

b. **Annual Center Progress Reports.** The recipient agrees to submit annual progress reports to the EPA Project Officer within 90 days after the end of each reporting period. Annual Technical and Financial Reports should discuss the activities of the *Center as a whole*. These reports must include, as applicable:

(1) A discussion of the research performed during the reporting period and results (outputs/outcomes) that have been generated.

(2) Difficulties the Center has (or might) encountered in carrying out its

mission, and remedial actions (to be) taken.

(3) A discussion of any absence or changes of key personnel involved in the individual projects or Center management. If the goals/hypotheses of any project funded under this Center have been modified from the original application, provide the revised goals and discuss the reason for the change.

(4) A discussion of expenditures to date along with a comparison of the percentage of the proposed work (e.g., setting up the Center or core functions, major projects) that is completed relative to the proposed schedules, and an explanation of any costs which are significantly higher than originally estimated.

(5) A discussion of how the quality assurance requirements of the following are being met: (1) 40 C.F.R 30.54; (2) G-1 STAR, *Guidance on Satisfying EPA Quality System Requirements for STAR Grants* (for individual projects), and (3) this agreement. *For more information on quality assurance see: http://es.epa.gov/ncer/guidance/* .

(6) Planned activities for the subsequent reporting period.

c. **Annual Project Summaries.** For *each* project funded under this grant, an annual project summary must be submitted with the annual Center progress reports. These will be placed on the EPA/NCER homepage. NCER will not alter the content of a summary without the approval of the Principal Investigator. The summary should be submitted in the format shown in ***Attachment A*** and need not be more than two pages.

d. **Final Center Report**. The recipient agrees to submit a final report to the EPA Project Officer by ninety calendar days after the expiration of the project period. The Project Officer may require clarifications of the final report before the report is accepted. This document must include:

(1) A discussion of the accomplishments/activities (outputs/outcomes) of the Center during the entire period of funding, describing achievements with respect to the mission of the Center, and incorporating quality assurance considerations.

(2) Details of any significant technical aspects of funded projects (both negative and positive) not included in the final *project* summaries.

(3) An evaluation of (a) the technical effectiveness and economic feasibility of the methods or techniques investigated, and/or (b) an explanation of how the funded research adds to our understanding of or solutions for environmental problems, or is otherwise of benefit to the environment and human health, written in terms understandable by the educated layman.

(4) For projects involving computer modeling, a statement that the recipient agrees to retain the following information in the research file:

(a) Model description and key assumptions;

(b) Performance criteria for the model (related to the intended use);

(c) Test results to demonstrate the model performance criteria were met (e.g., code verification, sensitivity analyses, history matching with lab or field data, as appropriate);

(d) Whether or not the theory and mathematical algorithms were peer reviewed, and, if so, a summary of theoretical strengths and weaknesses; and
(e) Documentation (e.g., users' guide, journal publications, code).

e. **Final Project Summaries.** The recipient agrees to submit project summaries for each funded research study with the final Center report. Summaries will be placed on the EPA/NCER Homepage along with a list of publications. NCER will not alter the content of a summary without the approval of the Principal Investigator. Each summary should be submitted in the format shown in ***Attachment B***, recommended at three to five pages.

f. **Form of Reports**. The recipient agrees to provide final and annual reports and associated summaries in an electronic format. The electronic versions shall be submitted in PC format, using commonly available word processing software or PDF. When requested by the Project Officer, these reports shall also be submitted in hardcopy format.

3. Human Subjects.

Should the Center support human subjects research under this grant, the following requirements apply:

a. According to the provisions of 40 C.F.R. 26, "Protection of Human Subjects," the recipient agrees to comply with EPA's testing and legally effective informed consent methods and procedures for safeguarding the rights and welfare of human subjects involved in approved projects.

b. Per 40 C.F.R. 26.118, no human subjects may be involved in this project(s) until it has been reviewed and approved by EPA's Human Subjects Research Review Official (HSRRO). For such approval, the recipient must forward: (1) proof of the institution's Human Subjects Institutional Review Board (IRB) approval and (2) copies of all other documentation forwarded to the IRB for its approval. Certification must be made by the IRB of the institution which proposes to conduct the work. The Project Officer will forward these to HSSRO for his review and approval. *No effort involving human subjects, including recruitment, may be initiated until EPA has approved the recipient's compliance with these requirements.*

c. The recipient must provide, as part of the Center annual report, evidence of the subsequent review(s) by the IRB as required by 40 C.F.R. 26.109(e) for any projects using human subjects.

d. Files for all projects involving human subjects must be kept by an individual within the Center who is charged by the Center Director with the responsibility of securing, approving, and recording IRB approvals.

e. The recipient agrees to comply with Subpart D, 45 CFR Part 46, "Additional DHHS Protections for Children Involved as Subjects in Research."

4. Quality Assurance/ Quality Control Program.

a. Within 60 days of acceptance of the award, the recipient agrees to provide a Quality Management Plan (QMP) to the Project Officer. This plan must be reviewed and approved by the EPA Project Officer prior to supporting any projects under this award. A QMP is a detailed policy statement describing the management and technical activities necessary to plan, implement and assess the effectiveness of the Quality Assurance (QA) system and Quality Control (QC) operations within the Center. This plan must be reviewed and approved by the EPA Project Officer. *For more information on QMPs, see http://www.epa.gov/quality/qmps.html.*

b. The Center Director will designate one individual within the organization to serve as Quality Assurance/Quality Control (QA/QC) Manager for the Center. This individual is responsible for coordinating the QA/QC activities and must keep complete files on all QA/QC plans for projects undertaken. No project will be supported under this award without prior review and written approval of the QA/QC plan for that project by the institution's QA Manager.

5. Publications, Abstracts and/or Other Public Release of Results.

a. The recipient agrees to provide copies of, or a reference for, any peer reviewed journal articles resulting from Center-sponsored research, in addition to the reports. EPA encourages the independent publication of the results of its extramural research in appropriate scientific journals. Any journal article so published, however, must contain the following statement:

"Although the research described in this article has been funded wholly or in part by the United States Environmental Protection Agency through grant/cooperative agreement (number) to (name), it has not been subjected to the Agency's required peer and policy review and therefore does not necessarily reflect the views of the Agency and no official endorsement should be inferred."

b. Because NCER intends to post references to all publications resulting from the agreement on its Home Page, the recipient is encouraged to continue to notify the Project Officer, after completion of the grant, of any papers that are published based on the research under the agreement.

c. An acknowledgment of EPA support must be clearly shown on Web pages and stated during all media interviews.

6. **Peer Reviews**.

a. EPA may elect to undertake periodic **independent peer evaluations** of the Center. At least 60 days notice will be provided before any such review is conducted. It is expected that the Center Director will cooperate fully with the peer review teams.

b. When required, an **activity status statement** must be submitted to the EPA Project Officer describing how the recommendations by any peer review have been implemented. This applies to peer reviews conducted by EPA before the award or during performance. The Center Director and EPA Project Officer will agree on the date the statement is due and the specific recommendations that must be addressed.

7. **Other Recipient Responsibilities.**

a. The Center Director and other appropriate Center personnel must attend an **annual meeting** with EPA personnel. The date and location of this annual meeting will be set by the EPA Project Officer, in consultation with the Center Director. Chairs of the Advisory Committee are also requested to participate in this annual meeting.

b. No institution may be added to or subtracted from the Center without the express written concurrence of the EPA Project Officer.

c. No **foreign travel** will be funded by this agreement without prior written approval of the EPA.

d. Although 40 CFR 30.25 (f) allows the recipient to grant itself a one-time **extension to the project period** under certain conditions, the recipient may not do so if, via this extension, the project period will exceed five years. Any extension of the expiration date which approaches five years must be requested at least thirty days in advance and approved by the Project Officer and Award Official. This approval is necessary due to certain Federal restrictions on the use of funds and the requirements of 40 C.F.R. 40.125-1. For any other extension the recipient is required to notify the EPA Award Official and Project Officer in writing, with the supporting reasons and revised expiration date, at least 10 days before the expiration date specified in the award.

e. **Program Income**. Program income is "gross income received by the grantee or subgrantee directly generated by a grant supported activity, or earned only as a result of the grant agreement during the grant period." Sources of program income include fees for services performed under the agreement, such as registration at conferences, and proceeds from sales of publications developed with assistance funds. If program income is generated under this agreement, the recipient will have the choice of allocating the income by adding to funds committed to the agreement (i.e., roll the funds back into the research effort), and/or use it to finance the non-Federal share of

the project.

Attachment A

NCER Assistance Agreement Annual Project Summary

Date of Report:
EPA Agreement Number:
Center Name & Internal Number:
Project Title:
Investigator(s):
Institution(s) of PI(s):
Research Category:
Project Period:
Objective of Research:
Progress Summary/Accomplishments:
Publications/Presentations:
Future Activities:
Supplemental Keywords:
Relevant Web Sites:

Attachment B

NCER Assistance Agreement Final Project Summary

Date of Final Report:
EPA Agreement Number:
Center Name & Internal Number:
Project Title:
Investigator(s):
Institution(s) of PI(s):
Research Category:
Project Period:
Description and Objective of Project:
Summary of Findings:
Conclusions:
Publications/Presentations:
Supplemental Keywords:
Relevant Web Sites:

NCER INTERNAL REVIEW SUMMARY

GAD Number: 83329301-0
Institution: Duke University
Principal Investigator (PI): Marie Miranda
RFA Title: Centers for Children's Environmental Health and Disease Prevention Research
Project Title: Southern Center on Environmentally-Driven Disparities in Birth Outcomes

Recommendation: FUND

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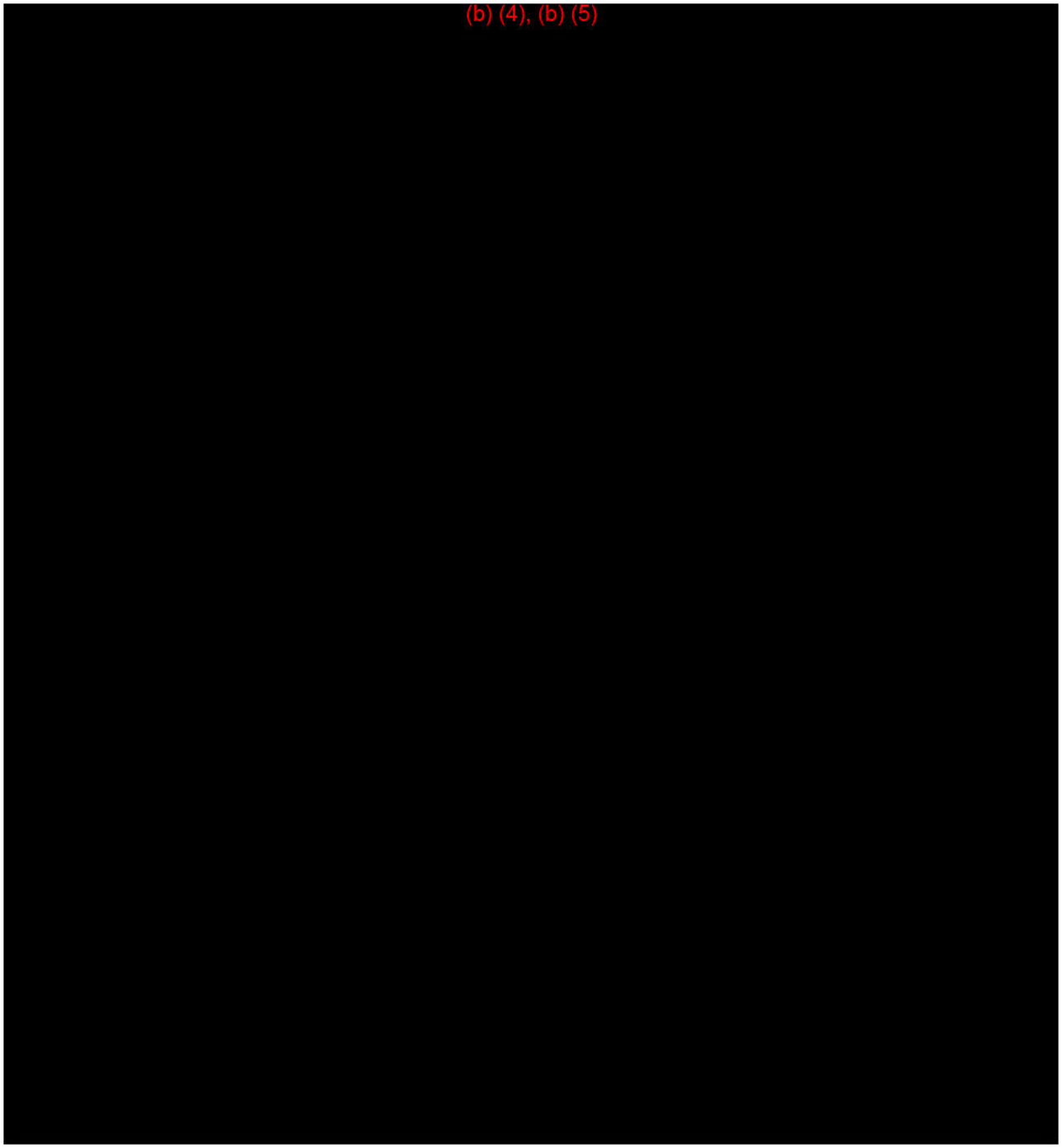

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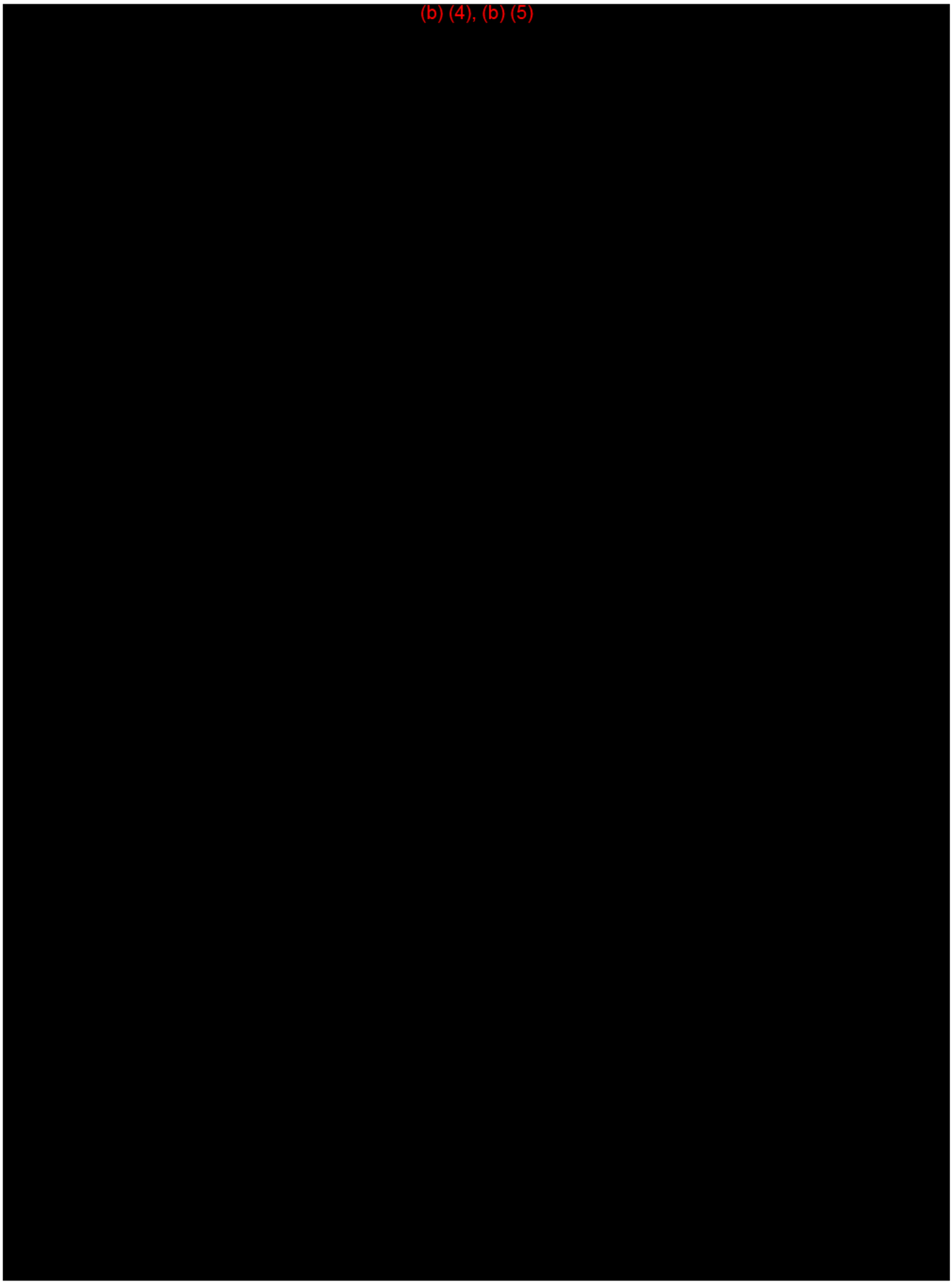
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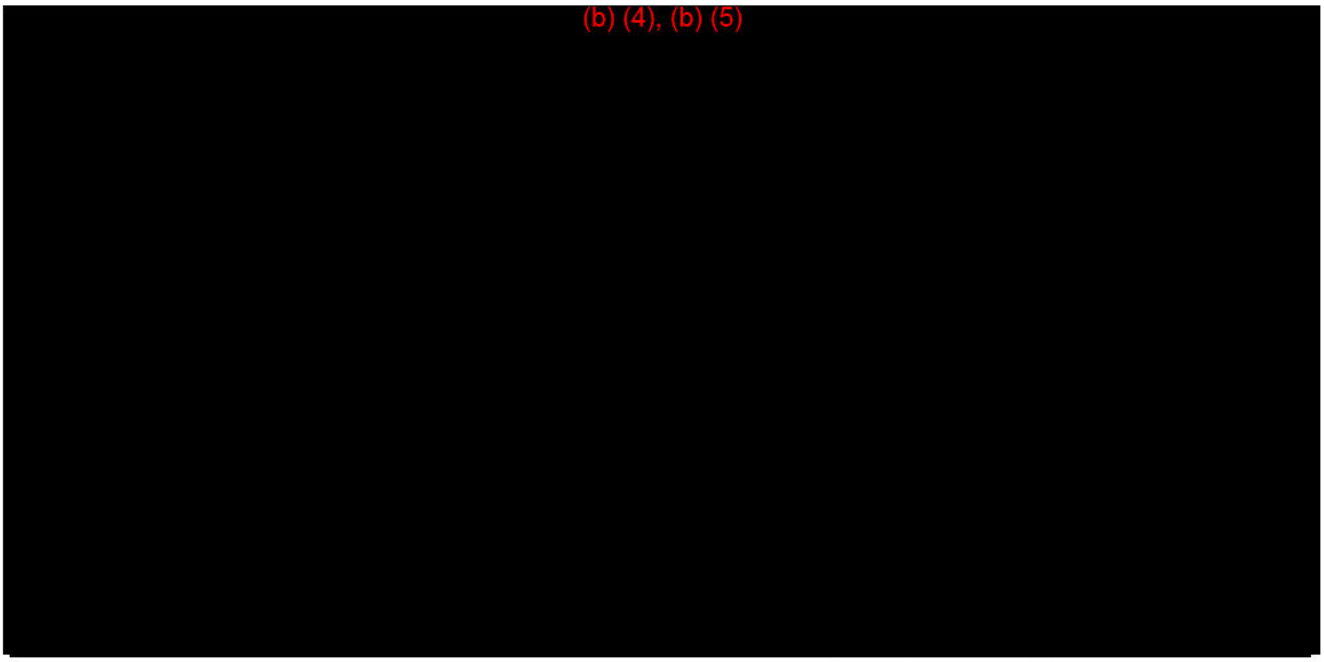

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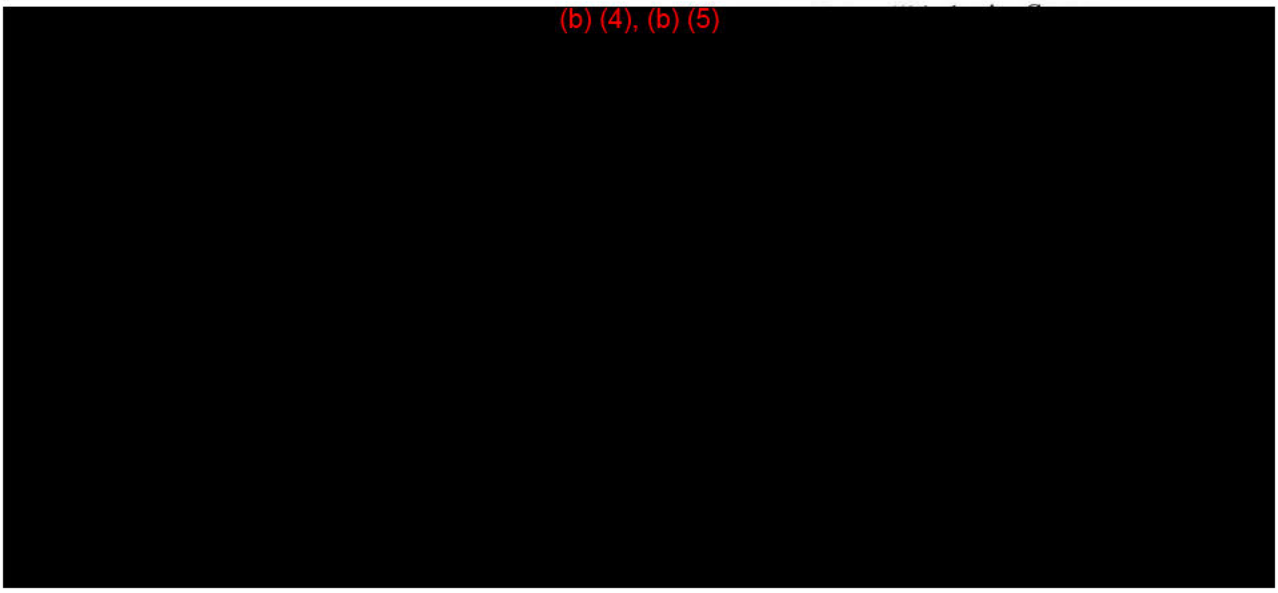

SCEDDBO will conduct basic mechanistic and applied research on understanding the environmental contributors to health disparities in birth outcomes. This will be achieved through the research infrastructure provided by the dedicated facility core, the mentoring of new investigators in the field of children's environmental health research, regular meetings of the Internal Steering Committee, regular meetings of research staff associated with the three research projects, a monthly informal chalk talk series, and enhanced communication among collaborating scientists and community members.

NCER, as part of its STAR program, issued a joint solicitation with the National Institute for Environmental Health Sciences (NIEHS) on October 11, 2005 entitled, "Centers for Children's Environmental Health and Disease Prevention Research". The solicitation asked for Research Center grants that would conduct multidisciplinary basic and clinical research using a community-based participatory approach to examine the effects of environmental exposures on children's health and to translate the research findings to public policy (see http://es.epa.gov/ncer/rfa/2005/2005_childrens_enviro_health.html). Two reviews were conducted as part of the evaluation process.

Grant applications were reviewed by an appropriate external technical peer review panel using the criteria summarized below and shown in Section V (Application Review Information) of the solicitation. All reviewers were required to sign a statement that they had no known conflict of interest.

Individual peer reviewers were asked to assign a priority score of excellent (100-150), very good (151-200), good (201-250), fair (251-350), or poor (351-500) to each application. NIEHS translated the average of these individual scores into the final panel review score. Peer review for scientific and technical merit emphasized two major aspects of the program project application: (1) review of the individual research projects and core unit(s), and (2) review of the program as an integrated research effort focused on a central theme.

The individual Center projects were evaluated on the basis of the following criteria:
(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? (2) Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
(3) Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?
(4) Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project? (5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

The Administrative Core was assessed based on the following criteria:
(1) The adequacy of the decision-making process within the proposed program for the evaluation of research productivity, allocation of funds, and management of the resources. (2) Evidence that the administrative core promotes joint planning and

evaluation activities as well as collaborations and interactions among different research cores of the program project. (3) Academic environment and resources in which the research will be conducted, including availability of space, equipment, human subjects, animals, or other resources as required, and the potential interaction with scientist(s) from other departments. (4) Institutional commitment to the requirements of the program project, including fiscal responsibility and management capability of the institution to assist the Principal Investigator and his/her staff in following EPA, DHHS, PHS, and NIH policy. (5) Appropriateness of the budget in relation to the proposed program project.

The Facility/Service Core(s) were assessed based on the following criteria:
(1) The core's utility to the program. Each core must provide services for two or more research projects judged to have substantial merit. (2) The quality of the facility or services provided. (3) The cost effectiveness of the service. (4) The qualifications of the personnel involved, their experience, and commitment to the core.

Additionally, the overall program was assessed based on the following criteria:
(1) The cohesiveness and multidisciplinary scope of the program and the coordination and interrelationship of all the individual research projects and cores to the common theme of the program. (2) The scientific gain of combining the component parts into a program project. (3) The presence and quality of mechanisms for regular communication and coordination among investigators. (4) For new applications, the synergy (degree of interaction, collaborative research opportunities) which will be stimulated by the program and how the research projects and cores relate to the central theme and the ability of the program to meet its long range goals. (5) The scientific merit of each individual project in the context of the proposed program, (i.e., assessment of the importance of the ideas or aims, the rationale and originality of the approach, the feasibility of the methods and the value of the result). (6) The specific scientific objectives of each project that will benefit significantly from, or depend upon collaborative interactions with other projects in the program (i.e., objectives that can be uniquely accomplished, specific contributions to the accomplishments of objectives in other projects, objectives that can be accomplished with greater effectiveness and/or economy of effort, etc.).

In addition to the above criteria, the following items were considered in the determination of scientific merit and the priority score: (1) Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research. (2) Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. (3) Care and Use of Vertebrate Animals in Research. (4) Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

(b) (4), (b) (5)

[redacted]

All applications receiving scores of excellent or very good by the peer reviewers were subject to an internal programmatic review, as described in Section V (Application Review Information) of the solicitation, conducted by technical experts from the EPA. The internal programmatic review panel considered: (1) the relevance of the proposed science to EPA research priorities, (2) the Principal Investigator's past performance and reporting history and (3) the applicant's organizational experience. A summary of the internal programmatic review for this application is attached.

Final funding decisions were made by the NCER Director, considering the results of the peer and programmatic reviews. This application is one of two to be awarded under the solicitation. The funding for this application is consistent with the award amounts referenced in Section II (Award Information) of the solicitation. All original peer review documentation is on file with NIEHS. All original programmatic review documentation is on file and available from the Project Officer.